DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MDL 15-2641-PHX-DGC

Doris Jones, an individual,

No. CV-16-00782-PHX-DGC

Plaintiff,

v.

C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,

Defendants.

JURY INSTRUCTIONS

DATED: May 31, 2018

David G. Campbell United States District Judge

and G. Campbell

Members of the Jury: Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

Although there are two defendants in this case, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as "Bard." Unless otherwise stated, the instructions apply to both Bard and Mrs. Jones.

The evidence you are to consider in deciding what the facts are consists of:

- 1. the sworn testimony of the witnesses;
- 2. the exhibits that are admitted into evidence;
- 3. any facts to which the lawyers have agreed; and
- 4. any facts that I have instructed you to accept as proved.

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and facts to which the parties have agreed. Which I have instructed you to accept.

Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

- 1. Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.
- 2. Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.
- 3. Testimony that is excluded or stricken, or that you were instructed to disregard, is not evidence and must not be considered. In addition, some evidence is received only for a limited purpose; when I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.
- 4. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

Some exhibits admitted into evidence have been partially "redacted," which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

The FDA's review of a medical device depends on how the device is classified under FDA regulations.

Certain devices are reviewed under the FDA's Pre-Market Approval (PMA) process, under which the FDA "approves" a device after finding that it is safe and effective.

Other devices, including the filters at issue in this case, are reviewed under the FDA's 510k process, under which the FDA "clears" a device after finding that it is "substantially equivalent" to another device already on the market. The device already on the market is known as the "predicate device."

FDA determines whether a device is substantially equivalent to a predicate device using the following criteria:

- (1) The device has the same intended use as the predicate device; and
- (2) The device either:
 - (a) Has the same technological characteristics as the predicate device; or
- (b) Has different technological characteristics, but the data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as the predicate device and does not raise different questions of safety and effectiveness than the predicate device.

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties, without authorization of the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

All parties are equal before the law and a corporation is entitled to the same fair and conscientious consideration by you as any party.

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

Mrs. Jones asserts three claims against Bard: (1) Product Liability Based on Design Defect; (2) Strict Product Liability Based on Failure to Warn; and (3) Negligent Failure to Warn. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

Before I give you instructions about Mrs. Jones' specific claims, let me give you a few instructions that will apply to all of the claims.

When a party has the burden of proving any claim or affirmative defense by a "preponderance of the evidence," it means you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not true. You should base your decision on all of the evidence, regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the "proximate cause" of Mrs. Jones' injury. Proximate cause means that cause which, in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural or ordinary course of events, produced Mrs. Jones' injury.

In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event, or some similar event, might reasonably result.

There may be more than one proximate cause of an event. Thus, to prove proximate cause, Mrs. Jones need not prove that an act or omission was the only cause or the last or nearest cause. It is sufficient if it combines with another cause resulting in the injury.

Mrs. Jones contends that Bard is liable because of a defective design of the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on my instructions and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

- 1) the usefulness of the product;
- 2) the severity of the danger posed by the design;
- 3) the likelihood of that danger;

- 4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;
- 5) the user's ability to avoid the danger;
- 6) the technology available when the product was manufactured;
- 7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;
- 8) the feasibility of spreading any increased cost through the product's price;
- 9) the appearance and aesthetic attractiveness of the product;
- 10) the product's utility for multiple uses;
- 11) the convenience and durability of the product;
- 12) alternative designs of the product available to the manufacturer; and
- the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

- 1) the availability of an alternative design at the time Bard designed this product;
- 2) the level of safety from an alternative design compared to the actual design;
- 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;
- 4) the economic feasibility of an alternative design;
- 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and

6) any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety and non-safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the Eclipse filter was defective, you may also consider whether the FDA instituted regulatory action with respect to the Eclipse filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Mrs. Jones contends that Bard is strictly liable because it failed to give adequate warnings regarding the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on an inadequate warning, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard; and

Third, the inadequate warning was a proximate cause of Mrs. Jones' injury.

There is no single general way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be determined by you, the jury, based on my instructions and the evidence received during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its Eclipse IVC filter. Bard owes this duty to warn to all physicians whom the manufacturer should reasonably foresee may use the product. Bard's duty to warn may have been breached by:

- a) failing to provide an adequate warning of the Eclipse filter's potential dangers or
- b) failing to adequately communicate to Mrs. Jones' physicians the warning provided.

A manufacturer's duty to warn arises when the manufacturer knows or reasonably should know of the danger presented by the use of the product. A manufacturer has a

continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard, to the physician who implanted the Eclipse filter in Mrs. Jones, and whether the warning that Bard communicated was adequate.

A product, however well or carefully made, that is sold without an adequate warning of such danger, may be said to be in a defective condition. If you find by a preponderance of the evidence that Bard did not adequately warn when an adequate warning should have been given, and that this inadequate warning proximately caused Mrs. Jones' injury, then you may find the Eclipse filter to be defective and for that reason, find that Mrs. Jones is entitled to recover.

Mrs. Jones claims that Bard was negligent in failing to warn about the risks of the Eclipse IVC filter Dr. Avino implanted in her. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to warn about the risks of the Eclipse IVC filter,
- (2) Bard breached that duty in the adequacy of the warnings about the Eclipse filter provided to Dr. Avino,
- (3) the breach was a proximate cause of Mrs. Jones' injury, and
- (4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

The parties agree that Bard had a duty of reasonable care to warn about the risks of the Eclipse IVC filter. If Mrs. Jones has failed to prove any other element by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses for removal of the Eclipse filter fragment, and that the expenses were proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Mrs. Jones seeks to recover for past physical pain and suffering for her hospitalization in April, 2015. She is not making any further claim for physical pain and suffering unless she has another procedure related to the filter. If you find that the evidence shows that it is more likely than not that Mrs. Jones will incur future pain and suffering, she would be entitled to recover an amount based on the enlightened conscience of fair and impartial jurors.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

- (1) interference with normal living;
- (2) interference with enjoyment of life;
- (3) impairment of bodily health and vigor;
- (4) fear of extent of injury;
- (5) shock of impact;
- (6) actual pain and suffering, past and future;
- (7) mental anguish, past and future; and
- (8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its liability will be increased by reason of the actual physical condition of the person toward whom the act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were proximately caused by Bard. No plaintiff, however, may recover for injuries that are not proximately caused by the defendant.

When a person is injured by the negligence of another, she must mitigate her damages as much as is practicable by the use of ordinary care and diligence.

If you find that Mrs. Jones has suffered damages as alleged, under the law, she is bound to reduce those damages, as much as is practicable, by the use of ordinary care. If you believe that by the use of such care that she could have reduced the damages, you would determine to what extent and reduce such damages to that extent.

In cases such as this, there may be aggravating circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to punish, penalize, and deter wrongful conduct.

Before you may award punitive damages, Mrs. Jones must prove that the actions of Bard showed willful misconduct, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences.

Mrs. Jones must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of "beyond a reasonable doubt," which is the proof required in criminal cases. Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

If Mrs. Jones fails to prove by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere negligence, even amounting to gross negligence, will not alone authorize an award of punitive damages.

In the verdict form, you will be asked to specify whether Mrs. Jones is entitled to recover punitive damages, but you will not yet be asked to determine an amount of punitive damages. If you decide that she should be awarded punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this case unless there is first a recovery by Mrs. Jones of compensatory damages.

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict, whether for the Plaintiff or for the Defendant, must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right, or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations:

Do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via email, via text messaging, or any internet chat room, blog, website or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the court.

Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the Internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, and do not use Internet programs or other devices to search for or view any place discussed during the trial. Also, do not do any research about this case, the law, or the people involved – including the parties, the witnesses or the lawyers – until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom, or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start

over. If any juror is exposed to any outside information, please notify the court immediately.

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, projector, printer and accessory equipment will be available to you in the jury room.

A court technician will show you how to operate the computer and other equipment; how to locate and view the exhibits on the computer; and how to print the exhibits. You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you were attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury shall not deliberate. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the Internet or to any "outside" website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. No member of the jury should ever attempt to communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in open court with the parties present. If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone – including the court – how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to the Court.

A verdict form has been prepared for you. [Explain verdict form as needed.] After you have reached unanimous agreement on a verdict, your foreperson should complete the verdict form according to your deliberations, sign and date it, and advise the bailiff that you are ready to return to the courtroom.

INSTRUCTION A

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

- 1) the nature and reprehensibility of Bard's conduct;
- 2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;
- 3) the intent of Bard in committing the wrong;
- 4) the amount of compensatory damages you have previously awarded;
- 5) the financial circumstances, that is, the financial condition or the net worth of Bard.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

- 1) the harm caused was physical, as opposed to economic;
- 2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and
- 3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.